

REMARKS

Claims 1-6, 8-19, 21-32, 34, 35, 37, 47, 50, 57, 60, 62-78, 80, 83, 85 and 87 are pending in this application. Upon entry of the amendments, claims 1-6, 8-15, 17-18, 25, 26, 28, 47, 57, 62-63, 66-78, 80, 83, 85 and 87 are withdrawn, claims 16, 26, 28 and 37 are amended, and claims 7, 20, 33, 36, 38-46, 48, 49, 51-56, 58, 59, 61, 79, 81, 82, 84 and 86 are canceled. Reference is made to the published application, unless otherwise noted.

Claim 16 is amended to recite “25-98%” by weight of composition of water. Support for this amendment is found at paragraph [0027]-[0053].

Claim 16 is amended to recite that the hydrophobic solvent is “petrolatum-free”. Support for this amendment is found at paragraph [0003].

Claims 26, 28 and 37 are amended to provide proper antecedent basis or to correct typographical errors.

No new matter has been added.

I. Species Election

Applicants note that the Office Action considers claims 17, 18, 25, 26, 28, 47, 57, 62, and 63 as withdrawn from consideration. As these claims are directed to non-elected *species* (as compared to a non-elected *invention*), applicants request that they be rejoined and considered at this time as depending from generic claim 1. Alternatively, applicants request that the claims be rejoined upon indication of patentable subject matter.

II. Indefiniteness Rejection

Claim 19 is rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly claim the subject matter of the invention. The Office Action states that it is unclear how a foamable composition with the percentages as set forth in claim 19 is possible, since the lowest percentage for all 5 ingredients is 100.3%.

Claim 16 has been amended to recite “25-98% water, so that the lowest percentages of all 5 materials in claim 19 is less than 100%. Withdrawal of the rejection is requested.

II. Rejections Under 35 U.S.C. § 103(a)

Claims 16, 19, 21-24, 27, 29-32, 34, 35, 37, 50, 60 and 64-65 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Abram (U.S. 6,730,288, in which PCT pub date is 03/23/2000) in view of Reed et al. (U.S. 6,299,900) and Shahinpoor et al. (U.S. 2002/0182162).

Independent claim 16 is set forth in the listing of claims. Claims 19, 21-24, 27, 29-32, 34, 35, 37, 50, 60 and 64-65 depend directly or indirectly from claim 16, and therefore include all of the limitations of claim 16.

The instant claims are directed to a pharmaceutical composition including an active agent, compressed gas propellant, and a foammable carrier including about 2-75 wt% a *petrolatum-free, liquid*, non-volatile hydrophobic solvent; about 25-98 wt% water; about 0.1 wt% to 5 wt% foam adjuvant; about 0.1 wt% to 5 wt% surface-active agent; and about 0.1 wt% to 5 wt% by weight of composition water gelling agent (all percentages by weight of composition. The instant claims are also directed to a thermally stable breakable foam that collapses upon application of sheer force.

The Office Action considers that Abram discloses all the elements of the claimed invention, except using an active agent – for which it relies on Reed and Shahinpoor. For the reasons detailed below, one of ordinary skill in the art could not find a teaching, suggestion, or motivation in the cited references to pick and choose the materials disclosed in the cited references to arrive at Applicants’ claimed method without relying on impermissible hindsight based on Applicants’ present disclosure (*see MPEP § 2141.01 (III) at 2100-121*).

The Office Action asserts that Abram discloses a “liquid, non-volatile hydrophobic solvent,” relying on disclosure of several “[s]uitable occlusive agents” at col. 2, lines 42-45 that include mineral oils. However, it seems that the statement has been taken out of context. When read as a whole, including the teaching and direction of the working Examples, it is clear that Abram does not

teach or suggest *liquid* hydrophobic solvents as an occlusive agent but on the contrary it directs a man of the art to use substantial amounts of a *solid* occlusive agent, e.g., in an amount sufficient to provide an occlusive effect. Abram discloses:

Suitable occlusive agents may be selected from one or more of the group consisting of mineral oils and *greases*, *long chain acids*, animal *fats* and *greases*, vegetable *fats* and *greases*, water insoluble *polymers* and the like. In a preferred embodiment the occlusive agent is petrolatum.

Column 2, lines 42-46. (Emphasis added.) Each and every one of the suitable occlusive agents listed in this passage is a *solid*, with the exception of mineral oils (which can be solid or liquid). Abram states that “[i]n a *preferred embodiment* the occlusive agent is petrolatum” (Abram at col. 2, lines 45-56, emphasis added). All of Abram’s examples contain petrolatum (*see* Table 1 in col. 4). Abram’s example 2 demonstrates that the more petrolatum that is included in the composition, the more effective the composition becomes (“[i]ncreasing concentrations of petrolatum in topical mousse formulations containing 0.05% clobetasol was able to increase the in-vitro human epidermal penetration of the steroid in both intact and stripped skin models” (col. 6, lines 2-5)). So it is clear that petroleum is not merely a preferred component it is an essential component. Thus, Abram teaches the use of *solid* occlusive agents and not *liquid* hydrophobic solvents. While liquid hydrophobic solvent can be used as a *co-solvent* (e.g., alkyl benzoate or caprylic/capric triglycerides), they necessarily occur in the presence of a substantial amount of petrolatum.

By advocating the use of skin occluding agents, in fact, Abram teaches away from the instant invention. Thus one of ordinary skill in the art, after reading Abram, would be especially motivated to select petrolatum-based compositions to form an occlusive barrier layer and to deliver an active agent and would be taught away from compositions lacking high levels of petrolatum. In contrast, the instant claims specifically exclude petrolatum, noting the disadvantages of such occlusive layers, in particular, petrolatum-containing layers.

For instance, ointments containing white petrolatum, e.g., Vaseline petroleum jelly, as the carrier often form an impermeable barrier, so that metabolic products and excreta from the wounds to which

Amendment dated December 14, 2009

Reply to Office Action of September 14, 2009

they are applied are not easily removed or drained away. Furthermore, it is difficult for the active drug dissolved in the carrier to pass through the white petrolatum barrier layer into the wound tissue, so the efficacy of the drug is reduced.

Instant specification at Paragraph [0003].

The Office Action also asserts that Abram discloses the use of polymeric gelling agents, based upon a passing reference to conventional pharmaceutical adjuvants such as "viscosity modifying agents." There is no teaching of polymeric gelling agents as recited in claim 16. The Office Action assertion that "viscosity modifying agents" reads on "water gelling agents", much less "about 0.1% to 5% by weight of composition [of a] water gelling agent," is not well taken. Viscosity modifying agents encompass a range of materials and functionalities. For example, viscosity modifying agents could either increase or decrease viscosity or change the response of the composition to various rheological forces, such as shear. It is not clear from the teaching of Abram that water gelling agents are contemplated as 'viscosity modifying agent', if for no other reason that Abram does not state what desired effect his viscosity modifying agent is intended to achieve. Abram most certainly does not provide a specific disclosure to prepare foamable compositions using water gelling agents.

Water gelling agents are used to stabilize the aqueous phase of the emulsion (see paragraph [0107]), which is not taught or suggested by Abram. Moreover, the specification clarifies another aspect of the relevance of the gelling agent as follows:

The combination of a surface active agent, foaming adjuvant and *water gelling agent* according to one or more embodiments of the invention provides a low specific gravity foam having superior flow properties and sheer breakability (among other attributes). Paragraph [0120].

Reed and Shahinpoor do not cure the deficiencies of Abram. The cited references do not teach or suggest foams and are only relied upon to teach the delivery of various active agent to a surface. In fact, Reed is directed to non-occlusive delivery vehicles and thereby teaches away from its combination with Abram (direct to occlusive carriers).

In view of the above amendment, applicant believes the pending application is in condition for allowance. Accordingly, Applicants submit that this rejection of claims 16, 19, 21-24, 27, 29-32, 34, 35, 37, 50, 60 and 64-65 under 35 U.S.C. § 103(a) has been overcome, and request that it be withdrawn.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 08-0219, under Order No. 0113873.00124US2 from which the undersigned is authorized to draw.

Respectfully submitted,

Dated: December 14, 2009


Mary Rose Sczzafava
Registration No.: 36,268
Attorney for Applicant(s)

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109
(617) 526-6000 (telephone)
(617) 526-5000 (facsimile)